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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,801	01/11/2002	Jackie Y. Ying	M00925/70110	4734

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EXAMINER	
KOSLOW, CAROL M	

ART UNIT	PAPER NUMBER
1755	

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/044,801	YING ET AL.	
	Examin r	Art Unit	
	C. Melissa Koslow	1755	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *581-599,601-612,614-621,623-639 and 674-695* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *581-599,601-612,614-621,623-639 and 674-695* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

This action is in response to applicants' amendment of 5 May 2003. The amendment to the claims caused the withdrawal of the 35 USC 251 new matter rejection, the 35 USC 112, first paragraph written description rejections, the 35 USC 112, second paragraph rejections and the art rejections over the commercially available Aldrich composition taught in the specification. Applicants' arguments with respect to the 35 USC 112, first paragraph enablement rejections were convincing and thus these rejections are withdrawn. Applicants' arguments with respect to the rejections over U.S. Patent 4,497,075 and U.S. patent 4,429,691 were convincing and thus the rejections over these references are withdrawn. Based on applicants' arguments over U.S. Patent 4,497,075 and U.S. patent 4,429,691, the 35 UCS 102(b) rejection over Nagai et al has been changed to a 35 USC 103 rejection. Applicant's arguments with respect to the remaining rejections have been fully considered but they are not persuasive.

The supplemental paper correctly amending the reissue application is accepted.

The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 6,013,591 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

Claims 581-599, 601-612, 614-621, 623-639 and 674-695 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc.* v. *Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement,* 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp.* v. *United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

Applicants added the limitations that the apatite crystals in the particulate are spherical and that the average apatite crystal size is less than 100 nm to obtain the original patent. Since the newly presented claims do not include the crystal shape limitation and includes average crystal sizes that are 100 nm and greater, the new added claims are broader than the patent claims and since the limitations now being omitted or broadened in the present reissue were originally presented and argued in the original application to make the claims allowable over a rejection made in the original application, the omitted limitations in the newly added claims relate to subject matter previously surrendered by applicant, and impermissible recapture exists. See MPEP 1412.02.

Applicants' analysis in section D of their amendment is incorrect. Improper recapture can occur even in claims that are of intermediate scope. See MPEP 1412.02. This section of the MPEP teaches reissue claims that are broader in certain aspects and narrower in others vis- à-vis claims canceled from the original application to obtain a patent may avoid the effect of the recapture rule if the claims are broader in a way that does not attempt to reclaim what was surrendered earlier. *Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 994, 27 USPQ2d 1521, 1525 (Fed. Cir. 1993). "[I]f the reissue claim is as broad as or broader in an aspect germane to a prior art rejection, but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim; [] if the reissue claim is narrower in an aspect germane to [a] prior art rejection, and broader in an aspect unrelated to the rejection, the recapture rule does not bar the claim, but other rejections are possible." *Clement*, 131 F.3d at 1470, 45 USPQ2d at 1165. The present claims are broader than the original claims and the newly added particle size limitations and properties of the article do not modify the claims such that the scope of the claims do not result in recapture of the surrendered subject matter of the average crystal size and shape. Applicants cited case law all deal with situations where the narrowing limitations modify the claims such that they scope of the claims no longer result in recapture. The rejection is maintained.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 620, 622, 623 and 626-630 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarcho.

This teaches apatite articles having an average XRD crystal size range of 200 nm to 3 microns, a density greater than 98% and a compression strength of about 90,000-150,00 psi or about 620-1034 MPa. These articles can be prosthesis, a coating for prosthesis or dental implants, all of which have a dimension of at least 0.5 cm. The density, strength and dimensions fall within the claimed ranges and an average XRD crystal size range that overlaps the claimed range. Product claims with numerical ranges which overlap prior art ranges were held to have been obvious under 35 USC 103. *In re Wertheim* 191 USPQ 90 (CCPA 1976); *In re Malagari* 182 USPQ 549 (CCPA 1974); *In re Fields* 134 USPQ 242 (CCPA 1962); *In re Nehrenberg* 126 USPQ 383 (CCPA 1960). The reference suggests the claimed article.

Applicants' arguments are not convincing. The taught overlapping range from 200 to less than 250 nm is a *prima facia* case of obviousness. The fact the reference does not recognize the importance of an average XRD crystal size range of less than 200 nm does not overcome this showing of *prima facia* obviousness. The fact the reference does not exemplify articles having an average XRD crystal size in the claimed range does not overcome the rejection. A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982). The rejection is maintained.

Claims 581-586 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagai et al.

Nagai et al teach apatite particulates having an average crystal size range of about 5-90 nm. This range falls within the claimed ranges. The reference teaches the mean particle size of the crystals or particles is 4-20 microns. Column 8, lines 29-31 teaches it is known in the art to use hydroxyapatite particles having a particle size in the range of 0.01-100 microns to produce

implants. Thus this teaching suggests to one of ordinary skill in the art that the taught particles can be milled from the taught average particle size to a smaller one that falls within the range of lines 29-31. This range overlaps the claimed range. While the surface area for these particulates are not taught, one of ordinary skill in the art would expect them to have a surface area range that falls within that claimed, absent any showing to the contrary, since the crystal ranges falls within the claimed range. Product claims with numerical ranges which overlap prior art ranges were held to have been obvious under 35 USC 103. *In re Wertheim* 191 USPQ 90 (CCPA 1976); *In re Malagari* 182 USPQ 549 (CCPA 1974); *In re Fields* 134 USPQ 242 (CCPA 1962); *In re Nehrenberg* 126 USPQ 383 (CCPA 1960). The reference suggests the claimed composition.

Applicant's amendment and arguments necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Koslow whose telephone number is (703) 308-3817. The examiner can normally be reached on Monday-Friday from 8:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell, can be reached at (703) 308-3823.

The fax number for Amendments filed under 37 CFR 1.116 or After Final communications is (703) 872-9311. The fax number for all other official communications is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661 or (703) 308-0662.

cmk
June 2, 2003

C. Melissa Koslow
Primary Examiner
Tech. Center 1700